

**REMARKS**

Claims 1-59 are pending in this case and claims 31-59 were withdrawn from consideration pursuant to a restriction requirement. Claim 1 was amended to recite that the polyamino acid derivative of formula (I) and salts thereof are the only anti-seborrhoeic agents applied to the area in need of treatment, and claim 25 was amended to correct the antecedent basis. Support for these amendment can be found, for example, on pages 2, 3 and 16-20 of the specification, and claims 1-25 as originally filed.

In this Office Action, the Office rejected claims 1-30 under 35 U.S.C. § 112, first and second paragraphs, and claims 1-10, 12-15, 25-27, and 30 under 35 U.S.C. § 103(a) and 35 U.S.C. § 102(e).

**I. Rejection under 35 U.S.C. § 112, first paragraph**

The Office rejected claims 1-30 under 35 U.S.C. § 112, first paragraph. In particular, the Office stated that "applicants' disclosure does not reasonably provide enablement for all 'disorders associated with seborrhoea and disorders associated with microorganisms of the genus *Propionibacterium*' as recited in claim 1." Office Action, page 2, paragraph 3. Applicants respectfully disagree and traverse the rejection for the following reasons.

The test for enablement is whether, if experimentation is necessary, it is undue. *In re Angstadt*, 537 F.2d 498, 504, 190 U.S.P.Q. 214, 219 (C.C.P.A. 1976). An enablement inquiry considers, but is not limited to, the following factors: (A) the breadth of the claims; (B) the nature of the invention; (C) the state of the prior art; (D) the level of one of ordinary skill; (E) the level of predictability in the art; (F) the amount of direction

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provided by the inventor; (G) the existence of working examples; and (H) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. *In re Wands*, 858 F.2d 731, 737, 8 U.S.P.Q.2d 1400, 1404 (Fed. Cir. 1988); see also, M.P.E.P. 2164.01(a). The Office's analysis, however, must consider all the evidence related to each of these factors and any conclusions of nonenablement must be based on the evidence as a whole. *In re Wands*, 858 F.2d 731, 737, 8 U.S.P.Q.2d 1400, 1404, 1407 (Fed. Cir. 1988). Further, specific technical reasons are always required to support a *prima facie* case of lack of enablement. M.P.E.P. 2164.04.

In this rejection, the Office fails to consider all the evidence related to each factor. In fact, the Office only addresses two of the eight *Wands* factors -- level of predictability in the art and the amount of direction provided by the inventor. With regard to the level of predictability in the art, the Office contends that “[i]t would be *unpredictable* that the claimed method would be applicable to all disorders that are associated with seborrhoea and *Propionibacterium* which may be discovered in the future.” Office Action, page 3, paragraph 2 (emphasis added). This statement, however, is a conclusion and fails to be supported by evidence of unpredictability.

To the contrary, a PubMed®<sup>1</sup> search of the literature demonstrates that articles published in the United States and abroad relating to seborrhoea and *Propionibacterium* as early as 1952. For example, using the search term “seborrhoea,” over 1,500 bibliographic hits resulted, and using the term “*Propionibacterium*” produced over 4,000 hits. Thus, these particular skin disorders have been researched, documented, and

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<sup>1</sup> PubMed® is a well known database that provides access to bibliographic information that includes MEDLINE and OLDMEDLINE covering fields of general science, chemistry, medicine, nursing, dentistry, veterinary medicine, and the health care system.

published for a significant time period. Further, this provides evidence that there is detailed research regarding disorders related thereto, and should provide evidence of predictability.

The Office also contends that "there is no direction provided by applicants for one having ordinary skill in the art to predict the claimed method would be effective to all skin disorders associated with seborrhoea and the microorganisms of genus *Propionibacterium*." Office Action, page 3, paragraph 3. This statement is again a conclusion and fails to be supported by any evidence. The original application provides ample direction regarding the invention at least on pages 1-3 of the specification. Because the Office failed to establish a reasonable basis to question the enablement provided by the claims, Applicants respectfully request the withdrawal of this rejection.

## II. Rejection under 35 U.S.C. § 112, second paragraph

The Office also rejected Claims 1-30 under 35 U.S.C. § 112, second paragraph, as being *indefinite* for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Office Action, page 4, paragraph 3. Applicants respectfully disagree and traverse the rejection for the following reasons.

The essential inquiry for indefiniteness is "whether the claims set out and circumscribe a particular subject matter with a reasonable degree of clarity and particularity." M.P.E.P. 2173.02. As such, definiteness must be analyzed, "not in a vacuum, but in light of: (A) the content of the particular application disclosure; (B) the teachings of the prior art; and (C) the claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made." See *id.* Thus, as a matter of law, as long as the scope of the claim, when read

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in light of the specification, is clear to one of ordinary skill in the art, the definiteness requirement is satisfied. See M.P.E.P. 2171.

The Office states that claim 1 "seems to claim a method of applying a compound itself alone on the skin or scalp. The metes and bounds of the scope of the claims are not clear." Office Action, page 4, paragraph 3 (emphasis added).

Applicants respectfully disagree, and submit that claim 1 is crystal clear in what it recites: A process for treatment of at least one condition recited in the claim by application of at least one compound recited in the claim to an area in need of such treatment. In making this rejection, the Office does not demonstrate with supporting evidence that the boundaries of the claims are not capable of being understood especially in light of the content of the application disclosure, the prior art, and the ordinary level of skill in the art. Further, a broad claim, no matter how broad, is not indefinite for the purposes of Section 112, second paragraph, so long as the boundaries of the claims are capable of being understood. Meaning, breadth of a claim is not to be equated with indefiniteness. *In re Miller*, 441 F.2d 689, 169 U.S.P.Q. 597 (C.C.P.A. 1971). Therefore, the Office did not establish a reasonable basis to question indefiniteness and thus, Applicants respectfully request the withdrawal of this rejection.

In addition, the Office states that in claim 25, there is insufficient antecedent basis for the limitation "said composition." Office Action, page 4, paragraph 4. In response, Applicants amended claim 25 to recite "said a composition." Thus, Applicants respectfully request the withdrawal of this rejection.

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### III. Rejection under 35 U.S.C. § 103

The Office rejected claims 1-10, 12-15, 25-27, and 30 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,886,041 to Yu, et al. ("Yu, et al."). In particular, the Office contends that "it would have been obvious to one having ordinary skill in the art at the time the invention was made to have used the Yu composition comprising the polyamino acids such as glycylhistidine to treat acne as suggested by the reference because of an expectation of successfully treating the skin disorder." Office Action, page 5, paragraph 3. Applicants respectfully disagree for the reasons made of record (see, e.g., Response filed July 23, 2003, pages 26-29; Response filed, January 26, 2003, pages 4-6) and traverse this rejection for the following reasons.

In making this rejection, the Office fails to consider all the requirements for establishing a *prima facie* case of obviousness. Among other things, the Office fails to show that the reference teaches or suggests all the elements of the claimed invention. M.P.E.P. 2142-43.

In particular, the Office states that Yu, et al. teaches "... treat[ment] of skin disorders such as acne." Office Action, page 5, paragraph 1. In fact, Yu, et al. states that the invention alleviates conditions and disorders of "... dry skin, dandruff, acne, keratoses, psoriasis, eczema, pruritus, age spots, lentigines, melasmas, wrinkles, warts, blemished skin, hyperpigmented skin, kyperkeratotic skin, inflammatory dermatoses, skin changes associated with aging, and skin requiring cleansers." The Yu patent, Abstract (emphasis added). This laundry list encompasses a wide range of disorders resulting from ultraviolet radiation, polygenic inheritance patterns, reactions to endogenous and exogenous agents, liver functionality, various disease states, viral

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tumors, and/or progressing age. Thus, Yu, et al. is directed to almost anything affecting the skin.

Claims 1-10, 12-15, 25-27 and 30, however, relate specifically to seborrhoea, disorders associated with seborrhoea, and disorders associated with microorganisms of the genus *Propionibacterium*. The preamble of claim 1 recites "at least one condition chosen from seborrhoea and disorders of the skin and scalp, disorders associated with seborrhoea, and disorders associated with microorganism of the genus *Propionibacterium*." In this instance, the preamble is said to be "necessary to give life, meaning, and vitality to the claim." *Kropa v. Robie*, 187 F.2d 150, 152 (C.C.P.A. 1952). Thus, the preamble provides a limitation.

There is no clear and particular evidence of a suggestion that Yu, et al. teaches the treatment of "seborrhoea" and/or "microorganisms associated with *Propionibacterium*," other than the broad recitation directed to acne. Acne, as defined by Webster's Third New International Dictionary, is "any of several inflammatory diseases involving the oil glands and hair follicles of the skin." Webster's Third New International Dictionary 17 (2002). As such, the common, ordinary definition of acne encompasses a broad range of afflictions affecting the skin but does not expressly identify disorders associated with seborrhoea and/or *Propionibacterium*.

Moreover, claim 1 has been amended to recite that the "polyamino acid derivative of formula (I) and salts thereof are the only anti-seborrhoeic agents applied to the area in need of treatment". Yu, on the other hand, also fails to suggest this limitation.

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Thus, this rejection is improper and Applicants respectfully request the withdrawal of this rejection.

#### IV. Rejection under 35 U.S.C. § 102(e)

The Office rejected claims 1-10, 12-15, 25-27, and 30 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,395,284 to Thunemann ("Thunemann") in view of Aldrich (1996-97). The Office provided that "Thunemann teaches the use of poly-L-amino acids such as poly-L-lysine in stabilizing retinoic acid in a composition that is used to treat acne. Examiner notes that poly-L-lysine meets the limitation of instant claim 1, formula (I). The reference teaches that poly-L-amino acids are used for the complexation [sic] of Vitamin A acid. . . . Aldrich teaches that poly-L-lysine having average molecular weight in the range of 1K-70K is commercially available." Office Action, page 6, paragraph 1. Applicants respectfully disagree and traverse the rejection for the following reasons.

Under Section 102, "a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987); see also, M.P.E.P. 2131. In a Section 102 rejection, multiple references may be used only when the extra references are cited to: "(A) prove the primary reference contains an 'enabled disclosure'; (B) explain the meaning of a term used in the primary reference; (C) show that a characteristic not disclosed in the reference is inherent." M.P.E.P. 2131.01.

In this rejection, the Office fails to provide the basis for the Aldrich reference. Instead, the Office states that "[g]iven the general teaching of using poly-L-lysine in an

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acne treatment composition in Thunemann, *it would have been obvious* to one having ordinary skill in the art at the time the invention was made to have looked to the prior art such as Aldrich for the commercially available polyamino acids and make use the Thunemann invention to treat acne." Office Action, page 6, paragraph 1 (emphasis added). The Office first identifies that the rejection is under Section 102 but then, discusses the rejection as an obviousness rejection, under Section 103. Although the combination of two references may be acceptable under Section 102 given the appropriate use of the second reference, the Office fails to utilize the second reference in this manner and thus, the rejection is improper.

Even assuming the Office provided a proper Section 102 and/or 103 rejection, the Office fails to meet its burden using the abovementioned references. Thunemann fails to teach all the limitations found in claims 1-10, 12-15, 25-27, and 30 under Section 102 or under Section 103 in combination with the Aldrich reference. In particular, Thunemann provides a broad recitation stating that "Vitamin A is used for the external treatment of severe cases of acne . . ." and further, that a complex of Vitamin A and polyelectrolytes facilitate the immobilization of Vitamin A to the site of interest by conferring protection, solubility and transportation of the Vitamin A. Thunemann, Col. 1, II. 21-33 (emphasis added); Col. 1, line 31-Col. 2, line 45. Further, Thunemann provides that it is the polyelectrolytes, i.e., poly-L-lysine, that mimics Vitamin A's binding to specific retinoid-binding proteins that occurs in the body allowing for immobilization. *Id.* at Col. 1, line 40-Col. 2, line 18.

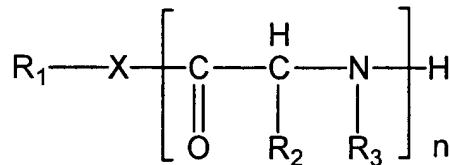
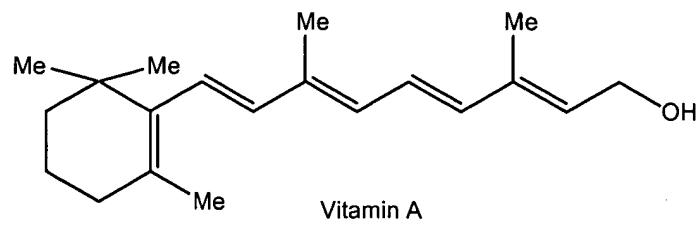
First, Thunemann clearly states that Vitamin A is the "pharmacological active substance" for the treatment of acne, not poly-L-lysine. Col. 1, II. 30-53. As such,

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Thunemann does not suggest or provide for the use of "polyelectrolytes," i.e., poly-L-lysine, as a viable composition used to generally treat disorders associated with seborrhoea and/or microorganisms of the genus *Propionibacterium*.

Second, Vitamin A, illustrated below, fails to meet the limitations of claim 1, formula (I).



formula (I)

Further, the use of Aldrich fails to cure the deficiencies in Thunemann. As characterized by the Office, Aldrich merely teaches the range of average molecular weights of poly-L-lysine. Office Action, page 5, paragraph 6. This disclosure along with that of Thunemann fail to teach all the limitations of claims 1-10, 12-15, 25-27, and 30 of the present application. For the abovementioned reasons, the rejection is improper and alternatively, the Office fails to satisfy its burden, and thus, Applicants respectfully request the withdrawal of this rejection.

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**CONCLUSION**

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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